

REMARKS

Reconsideration of the present Application in view of the above Amendments and following remarks is respectfully requested. Applicants acknowledge and thank the Examiner for indicating that claims 1 and 2 are allowable. Applicants have amended claims 4, 5, 8, 23, and 24 to more clearly point out and distinctly claim an embodiment of Applicants' invention and to place the claims in condition for allowance. New claims 26-29 were added to further increase the clarity of the claims and to expedite prosecution of this application; the new claims contain subject matter that had been recited in claims 5-8, respectively, prior to this amendment. Support for the amended claims may be found in the application as originally filed, for example, at page 3, lines 3-14; page 6, lines 16-22, and at page 50, line 22 through page 51, line 8. No new matter has been added.

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH (ENABLEMENT)

The Action rejects claim 4 and dependent claims 5-8 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Specifically, the Action asserts that undue experimentation would be required to determine how to make and use the claimed nucleic acid that comprises (1) a polynucleotide sequence that is complementary to a sequence encoding a polypeptide and (2) a polynucleotide sequence encoding a heterologous polypeptide.

Applicants respectfully traverse this rejection and submit that as disclosed in the present specification and recited in the instant claims, Applicants fully enabled the claimed invention at the time the Application was filed. Applicants submit that the specification enables a person skilled in the art to make and use, readily and without undue experimentation, an isolated nucleic acid molecule comprising (a) a nucleotide sequence that encodes a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2 or 13 and (b) a nucleotide sequence encoding a heterologous polypeptide (*see, e.g.*, page 2, lines 16-27; page 3, lines 4-6; page 31, line 17 through page 32, line 7). The instant disclosure further enables a skilled artisan to make and use an expression vector that comprises such a nucleic acid molecule, a host cell comprising such a vector, and a method for producing a polypeptide (*i.e.*, a fusion protein) comprising an ABCG4 transporter polypeptide having the amino acid sequence set forth in SEQ

ID NO: 2 or 13 and a heterologous polypeptide (*see, e.g.*, page 3, lines 3-6; page 31, line 17 through page 33, line 13; page 40, line 26 through page 46, line 15).

Accordingly, Applicants respectfully submit that the requirements for enablement under 35 U.S.C. § 112, first paragraph, are met and request that this rejection of the claims be withdrawn.

REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The Action rejects claims 8 and 23-24 under 35 U.S.C. § 112, second paragraph, for indefiniteness. In particular, the Action asserts that claim 8 is vague and indefinite with respect to which polypeptide is produced by the claimed method and that the nucleic acid of claim 4, upon which claim 8 depends, does not encode a polypeptide (see summary of enablement rejection above). The Action asserts that claim 24 recites SEQ ID NOS: 1, 3, and 12 as “antisense nucleic acid molecules” while the Sequence Listing states that the sequences are not complementary sequences. The Action further alleges that claims 23 and 24 are vague and ambiguous with respect to recitation of the term “suitable carrier” without stating an objective for which the carrier is suitable.

Applicants respectfully traverse these grounds for rejection and submit that the instant claims particularly point out and distinctly claim what Applicants regard as their invention. Applicants submit that in view of the amendments submitted herewith that include amendments to claim 8 and the addition of new claim 29, the claims more clearly point out that one embodiment of invention is directed to a method for producing a polypeptide comprising the amino acid sequence set forth in SEQ ID NO:2 or 13, wherein the method comprises culturing a host cell comprising an expression vector that contains a nucleic acid molecule, as recited, in an appropriate culture medium to thereby produce the polypeptide. Furthermore, Applicants submit that the claims more clearly point out that the subject invention is directed in another embodiment to a method for producing the polypeptide encoded by nucleic acid molecule comprising (a) a nucleotide sequence that encodes a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2 or 13 and (b) a nucleotide sequence encoding a heterologous polypeptide. Accordingly, Applicants submit that the claims are definite and thus meet the

requirements of 35 U.S.C. § 112, second paragraph, and respectfully request that the rejection be withdrawn.

Applicants respectfully traverse the rejection of claims 23 and 24 for indefiniteness and submit that the claims clearly point out and distinctly claim what Applicants regard as their invention. Specifically, with regard to the rejection of claim 24, Applicants respectfully disagree with the assertion in the Action that claim 24 refers to SEQ ID NO:1, 3, and 12 as antisense nucleic acid molecules. Nevertheless, solely to expedite prosecution of this Application, Applicants have amended claim 24 to recite even more clearly that the subject invention composition is directed in pertinent part to an antisense nucleic acid molecule that comprises (a) a nucleotide sequence that is complementary to a sequence encoding a polypeptide, which polypeptide comprises an amino acid sequence set forth in SEQ ID NO:2 or 13, *or* (b) a nucleotide sequence that is complementary to a sequence selected from the group consisting of SEQ ID NO: 1, 3, and 12.

Applicants further submit that in view of the amendments to claims 23 and 24, the claims clearly point out that the subject invention compositions comprise the antisense nucleic acid molecules as recited and a pharmaceutically acceptable carrier. A pharmaceutically acceptable carrier is a compound that is suitable for administration; such carriers are extensively described in the present specification (*see, e.g.*, page 6, lines 16-22; page 50, line 22 through page 51, line 8; *see generally* page 50, line 22 through page 55, line 13).

In view of the present amendments and the above remarks, Applicants respectfully submit that the instant claims meet the requirements for definiteness under 35 U.S.C. § 112, second paragraph. Applicants therefore request that the rejection of these claims be withdrawn.

Applicants respectfully submit that all remaining claims in the Application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. In the event that the Examiner believes a teleconference will facilitate prosecution of this case, the Examiner is invited to telephone the undersigned at 206-622-4900.

Respectfully submitted,

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